PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Heng Hang Tsai, et al.	Confirmation No.: 2216	
Serial No:	10/583,179		
Filed:	August 25, 2008	Group Art Unit: 1797	
Title:	PROTEIN SEPARATION DEVICE	Examiner: Dirk R. Bass	
Docket No:	490352-3004/US		

Mailstop - Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. § 1.56, § 1.97 and § 1.98, Applicant brings the references listed on the attached Forms PTO/SB/08a and PTO/SB/08b to the examiner's attention. These references may be material to examination of the above-identified application. Please do not construe the filing of this information disclosure statement as a representation that applicant has made a search (37 C.F.R. § 1.97(g)), or as an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists. Applicants enclose a copy of the translated Japanese Office Action, dated July 20, 2010, for the Examiner's reference.

This Information Disclosure Statement is being submitted:

☐ 1. Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or before the mailing date of a first office action on the merits, or before the mailing of a first office action after filing of a request for continued examination under 37 CFR 1.114, and therefore, Applicant believes no fee is required;

☒ 2. After the period specified in paragraph (1) hereinabove of this section, but is being filed before the mailing date of either a final action under 37 CFR 1.113, or a notice of

allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by one of the following:

☒ (a) A statement that either:

(i) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement;

OR

(ii) No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement;

OR

☐ (b) The fee of $180 for filing of an Information Disclosure Statement as set forth in 37 C.F.R. 1.17(p).

☐ 3. After the period specified in paragraph (2) of this section, but is filed on or before payment of the issue fee and is accompanied by both:

☐ (a) A statement that either:

(i) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement;

OR

(ii) No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement;

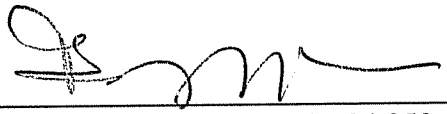
☐ (b) The fee of $180.00 for filing of an Information Disclosure Statement as set forth in 37 CFR 1.17(p).

Applicant would appreciate the Examiner initialing and signing a copy of Forms PTO/SB/08a and PTO/SB/08b, transmitted herewith, indicating that the information has been considered and made of record herein.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-1901** referencing order number 490352-3004/US.

Dated: October 21, 2010

Respectfully submitted,
OPPENHEIMER WOLFF & DONNELLY LLP

By 

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(Translation)

Mailed: July 20, 2010

NOTICE OF REASONS FOR REJECTION

Patent Application No. : 2006-545304

Examiner's Notice Date : July 9, 2010

Examiner : Hideo NOMURA

Representative for Applicant: Mr. Takehiko SUZUYE (and 11 others)

Applied Sections : 29 (main paragraph), 29(1), 29(2), 36

This application is rejected on the grounds stated below. Any opinion about the rejection must be filed within THREE MONTHS of the mailing date hereof.

REASONS

1. The inventions recited in the following claims of this application are unpatentable under the main paragraph of Section 29 (1) of the Patent Law as failing to satisfy the following requirements.

2. The inventions recited in the following claims are unpatentable under Section 29 (1) (iii) of the Patent Law as being described in the following publication distributed in Japan or a foreign country prior to this application or made available to the public through electric telecommunication lines in Japan or a foreign country prior to this application.

3. The inventions recited in the following claims are unpatentable under Section 29 (2) of the Patent Law, as being such that the inventions could easily have been made by a person with ordinary skill in the art to which the inventions pertain, on the basis of the inventions described in the following publications distributed in Japan or a foreign country prior to this application or the inventions made available to the public through electric telecommunication lines in Japan or a foreign country prior to this application.

4. The application fails to satisfy the requirements under Section 36 (4) (i) of the Patent Law, on the grounds that the Detailed Description of the Invention is defective in the following respects.

5. The application fails to satisfy the requirements under Section 36 (6)(i) of the Patent Law, on the grounds that the claims are defective in the following respects.

6. The application fails to satisfy the requirements under Section 36 (6)(ii) of the Patent Law, on the grounds that the claims are defective in the following respects.

REMARKS

(A)

* Reason 1

* Claims 47-49

The "method of diagnosis" in claim 47 corresponds to what is called "treatment action", and is not considered as "an industrially available invention".

Claims 48-49 are unallowable for the same reason.

(B)

* Reasons 2, 3

* Claims 1-2, 20, 25

* Reference 1

* NOTE

Reference 1 discloses a method of immobilization of peptides or proteins on a substrate in use for affinity chromatography isolation. More specifically, Reference 1 discloses immobilizing rat chaperonin 10 (cpn 10: corresponding to GroES of E. coli) on avidin beads via biotinylated N-terminal in the intended orientation (p. 256, right column, ll. 1-32, scheme 1 and the like), and also discloses that GroEL was obtained when a protein bound to the cpn 10 was isolated from a crude cell lysate using the beads as a chromatograph matrix (p. 256, right column, line 33 to p. 259, left column, line 2, FIG. 2 and the like).

It is therefore considered that the inventions recited in claims 1-2, 20, 25 are the same as the invention disclosed in Reference 1.

(C)

* Reasons 2, 3

* Claims 1-5, 13-17, 20, 25-28, 45

* Reference 2

* NOTE

Reference 2 discloses that a denatured enzyme such as GDH, etc. was renatured using a glass substrate having GroEL and GroES immobilized thereon (p. 104, right column, l. 15 to p. 107, right column, l. 23, FIG. 4-6 and the like). Reference 2 also discloses that since immobilized GroEL is bound to the denatured substrate, the matrix can be used to remove unfolded LDH, etc. from a solution (p. 108, right column, l. 28 to p. 109, left column, l. 4). Thus, Reference 2 is considered to substantially disclose a method of isolating the denatured protein by using a glass substrate having GroEL immobilized thereon.

It is therefore considered that the inventions recited in claims 1-5, 13-17, 20, 25-28, 45 are the same as the invention disclosed in Reference 2.

Even if they are not the same, the inventions recited in the claims could easily have been accomplished based on the descriptions of Reference 2 by a person of ordinary skill in the art.

(D)

* Reason 3

* Claims 1-49

* References 1-5

* NOTE

The invention recited in claim 5 and the invention disclosed in Reference 1 are the same in terms of being a protein separation device comprising a chaperone protein immobilized on a substrate, but are different in terms of a point that chaperone is GroEL in the former invention while it is cpn10 (GroES) in the latter invention.

However, a column having GroEL immobilized has been known as disclosed in, for example, References 2-3, etc., prior to the priority date of the present application.

Therefore, using GroEL instead of GroES as chaperone in the column disclosed in Reference 1 could easily have been accomplished by a person of ordinary skill in the art.

Incidentally, it has been so well known prior to the priority date of the present

application as to require no citation of references, that a chaperone protein such as GroEL, GroES, etc. interacts with a denatured protein, besides an GroEL and GroES. Then, a method of purifying a chaperone protein with a column having a denatured protein immobilized thereon is disclosed in References 4-5. In addition, a method of binding a denatured protein to a column having chaperone immobilized thereon is also considered to have been known as disclosed in, for example, References 2-3, etc., prior to the priority date of the present application.

Thus, a method of isolating a denatured protein by using a column having suitable chaperone such as GroEL, etc. immobilized thereon could easily have been conceived by a person of ordinary skill in the art.

It is not considered that effects of the claimed inventions are advantageous and heterogeneous, or homogenous but significantly superior to the prior art, and are so significant that they could not have been expected from the descriptions in References 1-5.

Claims 1-4 and 6-49 are unallowable for the same reason.

(E)

* Reasons 4, 5

* Claims 6-12, 49

Claim 6 recites a device using GroEL having a different multimeric configuration from natural GroEL.

However, a protein separation device comprising GroEL having such a desired configuration is not concretely described in the Detailed Description of the Invention. Thus, it cannot be understood from the Detailed Description of the Invention how a protein separation device having such a multimeric configuration can be manufactured.

Therefore, the Detailed Description of the Invention is not described so clearly or sufficiently as to enable a person of ordinary skill in the art to accomplish the inventions recited in the above claims.

In addition, it is not considered, with reference to the technically common

knowledge obtained at the filing of the present application, that the elements disclosed in the Detailed Description of the Invention can be expanded or generalized to the scope of the inventions recited in the claims. Therefore, the inventions recited in the claims are not considered as those described in the Detailed Description of the Invention.

Claims 7-12, 49 are also considered unallowable for the same reason.

(F)

* Reasons 4, 5

* Claims 32, 43-44

Claim 32 recites an invention relating to "a protein separation device comprising GroEL immobilized on a substrate in an optimized orientation to bind target protein and to provide minimal steric hindrance between GroEL and the substrate".

As such a device described with concrete basis in the Detailed Description of the Invention, however, biotin is bound to altered GroEL having aspartate at position 490 substituted with a cysteine and then bound to avidin, etc. on the substrate, and objective evidence supporting the fact that a protein separation device having a desired orientation can also be obtained in the other means is not concretely described in the Detailed Description of the Invention. Thus, trial and error and high-level complicated experiments need to be conducted to a degree higher than the expectation of a person of ordinary skill in the art, to bind a target protein and immobilize GroEL in a desired orientation to provide minimal steric hindrance between GroEL and the substrate, in a method other than the method using the biotin.

Therefore, the Detailed Description of the Invention is not described so clearly or sufficiently as to enable a person of ordinary skill in the art to accomplish the inventions recited in the above claims.

In addition, it is not considered, with reference to the technically common knowledge obtained at the filing of the present application, that the elements

disclosed in the Detailed Description of the Invention can be expanded or generalized to the scope of the inventions recited in the claims. Therefore, the inventions recited in the claims are not considered as those described in the Detailed Description of the Invention.

Claims 43-44 are also considered unallowable for the same reason.

(G)

* Reasons 4, 5

* Claims 36, 43

Claim 36 recites an invention relating to a protein separation device using "GroEL having the specificity directed to a particular protein."

Incidentally, to newly obtain a new substance having a desired specificity with reference to the technical common knowledge in this technical field, it is necessary to construct libraries having various variations and execute screening by actually conducting a test on whether they have desired activities. On the other hand, objective evidence supporting the fact that GroEL was concretely obtained as GroEL having the specificity directed to a particular protein is not concretely described in the Detailed Description of the Invention. It is not described that GroEL having particular substitution variation has the above-explained function, but concrete evidence supporting this matter is not described in the Detailed Description of the Invention. Furthermore, GroEL having the other structure is not described. Thus, trial and error and high-level complicated experiments need to be conducted to a degree higher than the expectation of a person of ordinary skill in the art, to actually obtain GroEL having the specificity directed to a particular protein.

Therefore, the Detailed Description of the Invention is not described so clearly or sufficiently as to enable a person of ordinary skill in the art to accomplish the inventions recited in the above claims.

In addition, it is not considered, with reference to the technically common knowledge obtained at the filing of the present application, that the elements disclosed in the Detailed Description of the Invention can be expanded or

generalized to the scope of the inventions recited in the claims. Therefore, the inventions recited in the claims are not considered as those described in the Detailed Description of the Invention.

Claim 43 is also considered unallowable for the same reason.

(H)

* Reasons 4, 5

* Claims 39, 41-42, 44

Claim 39 recites an invention relating to a protein separation device using "GroEL having the specificity changed to a protein specificity of another chaperone protein."

However, it is not considered that GroEL having the specificity changed to a protein specificity of another chaperone protein has been well known prior to the priority date of the present application. In addition, GroEL objectively supported as GroEL recited in the claim is not described in the Detailed Description of the Invention. Thus, trial and error and high-level complicated experiments need to be conducted to a degree higher than the expectation of a person of ordinary skill in the art, to manufacture a protein separation device comprising GroEL having the specificity changed to a protein specificity of another chaperone protein.

Therefore, the Detailed Description of the Invention is not described so clearly or sufficiently as to enable a person of ordinary skill in the art to accomplish the inventions recited in the above claims.

In addition, it is not considered, with reference to the technically common knowledge obtained at the filing of the present application, that the elements disclosed in the Detailed Description of the Invention can be expanded or generalized to the scope of the inventions recited in the claims. Therefore, the inventions recited in the claims are not considered as those described in the Detailed Description of the Invention.

Claims 41-42, 44 are also considered unallowable for the same reason.

(I)

* Reasons 4, 5

* Claims 47-49

Claim 47 recites an invention relating to "a method of diagnosis" comprising particular steps.

However, pharmaceutical test results objectively supporting the fact that some diseases were actually diagnosed in the steps, are not concretely described in the Detailed Description of the Invention.

Therefore, the Detailed Description of the Invention is not described so clearly or sufficiently as to enable a person of ordinary skill in the art to accomplish the inventions recited in the above claims.

In addition, it is not considered, with reference to the technically common knowledge obtained at the filing of the present application, that the elements disclosed in the Detailed Description of the Invention can be expanded or generalized to the scope of the inventions recited in the claims. Therefore, the inventions recited in the claims are not considered as those described in the Detailed Description of the Invention.

Claims 48-49 are also considered unallowable for the same reason.

(J)

* Reason 6

* Claims 25-31

Claim 25 recites "The protein separation device as claimed in any one of claims 1 to 25." This recitation is considered as a description error and should be "The protein separation device as claimed in any one of claims 1 to 24."

In addition, claim 25 recites "the biological sample". However, claims 1-24 do not have descriptions on "biological sample". Therefore, "the" is unclear.

Since the inventions recited in claims 25-31 relate to not a method, but a device, specifying the sample is not associated with the structure of the device, and

its technical relation with the device cannot be recognized. In other words, the description for specifying the sample is useless as an invention-specifying matter.

(K)

* Reason 6

* Claims 32, 36, 39, 41-44

The "protein separation device" recited in claim 32 is described with an only result to be achieved, i.e. "comprising in an optimised orientation to provide minimal steric hindrance between GroEL and the substrate", but its concrete solving means is not specified. Therefore, a person of ordinary skill in the art cannot concretely infer what structure GroEL has to possess such a property.

Claims 36, 39, and 41-44 are unallowable for the same reason.

References Cited:

1. BALL, H.L. et al., "Application of reversible biotinylated label for directed immobilization of synthetic peptides and proteins: isolation of ligates from crude cell lysates.", J. PEPT. SCI., July 1997, Vol. 3, No. 4, pp. 252-260

2. PRESTON, N.S. et al., "The production and characterisation of an immobilised chaperonin system.", BIOCHEM, BIOPHYS. ACTA, 4th January 1999, Vol. 1426, No. 1, pp. 99-109

3. DONG, X.Y. et al., "Lysozyme refolding with immobilized GroEL column chromatography.", J. CHROMATOGR. A, 12th May 2000, Vol. 878, No. 2, pp. 197-204

4. EVERS, M.E. et al., "Affinity purification of molecular chaperones of the yeast Hansenula polymorpha using immobilized denatured alcohol oxidase.", FEBS LETT., 19th April 1993, Vol. 321, No. 1, pp. 32-36

5. NAM, S.H. et al., "Affinity purification and characterization of the Escherichia coli molecular chaperones.", PROTEIN EXPR. PURIF., March 2002, Vol. 24, No. 2, pp. 282-291

<NOTE FOR AMENDMENTS>

(1) When the specification is amended, portions modified by the amendments should be underlined (Regulations under the Patent Law, note 13.6).

(2) Amendments must be made within the scope of the matters described in the specification or drawings originally attached to the present application or matters which are obvious from the matters described in the specification or drawings originally attached to the present application. In a Written Argument, the legality of amendments for the respective amended matters should be explained by clearly pointing the relevant portions of the specification and the like in the original application as bases of the amendments. (As for the description form of a written argument, please refer to the description form of a Request for Correction at an Invalidation Appeal stage.)

(3) The Suggestion of Amendments does not cause any legal effects, but is a mere option of amendments to overcome the rejection. The applicant should decide how to amend the specification and drawings.

(4) If a new reason for rejection is noticed, a further Official Action will be issued.

Prior Art Search Report

Searched Fields: IPC C07K1/00 - 19/00

DB Name CA / MEDLINE / BIOSIS (STN),
PubMed, WPI

Prior-Art Documents:

* Jpn. Pat. Appln. KOKAI Publication No. 7-48398

* International Publication No. 03/061570

* GAO, Y.G. et al., "On-column refolding of recombinant human interferon-gamma with an immobilized chaperone fragment.", BIOTECHNOL. PROG., May

2003, Vol. 19, No. 3, pp. 915-920

* VIITANEN P.V. et al., "Purified chaperonin 60 (groEL) interacts with the nonnative states of a multitude of Escherichia coli proteins.", PROTEIN SCI., March 1992, Vol. 1, No. 3, pp. 363-369

* PHADTARE, S. et al., "Refolding and release of tubulins by a functional immobilized groEL column.", BIOCHIM. BIOPHYS. ACTA, 21st September 1994, Vol. 1208, No. 1, pp. 189-192

* NIEBA, L. et al., "BIACORE analysis of histidine-tagged proteins using a chelating NTA sensor chip.", ANAL. BIOCHEM., 15th October 1997, Vol. 252, No. 2, pp. 217-228

The result of this prior art search does not constitute the reasons for rejection.

If the applicant has any questions or wishes to have an interview, please contact the following Examiner:

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